



DEPARTMENT OF HEALTH AND HUMAN SERVICES

d14946

Food and Drug Administration
Atlanta District Office

FI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

March 10, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Roy C. Mallady, Jr.
Chairman of the Board
Horizon Medical Products, Inc.
7 North Parkway Square
4200 Northside Parkway, NW
Atlanta, Georgia 30327

Warning Letter

Dear Mr. Mallady:

During an inspection of your firm located in Manchester, Georgia, on September 11 - October 17, 1997, our investigator determined that your firm manufactures and distributes various types of catheters. Your firm also is a specifications developer and own label distributor of implantable vascular access ports. Both, the catheters and the vascular access ports, are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21 of the Code of Federal Regulations (CFR), Part 820, and the Quality System Regulation, 21 CFR Part 820 which became effective June 1, 1997, as follows:

- ▶ Failure to assure that finished devices meet device specifications prior to release for distribution, in that the number of sterile devices selected per lot for bacterial endotoxins testing was less than the minimum required by the United States Pharmacopeia (USP) under their biological tests for "Transfusion and Infusion Assemblies". We disagree with your firm's interpretation that the required number of test devices can be obtained by selecting one out of each lot of closely related sterile devices. Your sampling procedure is not equivalent to that required by the USP.
- ▶ Failure to validate the QC leak testing procedures to assure leaks are detected in the various catheters manufactured.

Additionally, the above-stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to submit information to the Food and Drug Administration (FDA) as required by the Medical Device Reporting (MDR) regulation, as specified in 21 CFR Part 803. Specifically, you failed to submit MDR serious injury reports to FDA after receiving information which reasonably suggested that one of your commercially distributed devices had malfunctioned and caused or contributed to a serious injury. A serious injury MDR report is required for the following incidents identified in the above referenced inspection as complaints: 111, 124, and 130.

You have also failed to submit MDR malfunction reports to FDA after receiving information which reasonably suggested that one of your commercially distributed devices had malfunctioned and could cause or contribute to a serious injury if the malfunction recurred. An MDR malfunction report is required for the following incidents identified in the above referenced inspection as complaints: 112, 113, 120, 123, 133, 134, HO185, HO188, HO191, HO200, HO205, and HO210.

The MDR reports for those events described above should be submitted to the address below. Please be advised that when you submit retrospective reports you should include a cover letter describing the reports as retrospective submissions and the reason for the submission.

Division of Surveillance Systems (HFZ-533)
Office of Surveillance and Biometrics
Food and Drug Administration
1350 Piccard Drive
Rockville, Maryland 20850

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 (copy enclosed) issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge receipt of a letter (with attachments) from William E. Peterson, Jr., dated 10/27/97, and addressed to Ballard H. Graham, containing your firm's response to the form FDA 483. You may refer to it in your response to this one. Below are our comments to Mr. Peterson's letter:

Observation 3: In his letter, Mr. Peterson referred to the results of two validation protocols, i.e. 30 and 31, in support of his contention that all the pouches seal similarly regardless of their length or width differences. It is our understanding that the pouch studies undertaken under protocols 30 and 31 involved a different type of pouch sealer at another manufacturing site, not the Model [REDACTED] Sealer. Thus we

believe it is inappropriate to include those results as supporting evidence to the pouch sealer in question.

Observation 4: Although calibration and preventive maintenance of the leak testing equipment is very important, it is not equivalent or a substitute to validation of the leak testing procedures.

Observation 5: Response appears adequate.

Observation 6: It is acceptable to rely on a certificate of analysis from your J-Guidewire supplier, in lieu of doing the pull strength testing at your facility, as long as you verify periodically (e.g. audit visit once a year) that your supplier is doing adequate testing, and is producing a component that meets your specifications.

Observation 7: The 10/21/97 Material Specification for PVC Tubing submitted with the response does not specify the sampling plan, and the acceptable quality level in [REDACTED] to be used. It also lacks approval signatures and dates.


Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and or civil penalties.

Please notify this office by April 1, 1998, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed by the above date, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Carlos A. Bonnin, Compliance Officer, Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Enclosure

cc: William E. Peterson, Jr.
President
Horizon Medical Products, Inc.
P.O. Drawer 627
One Horizon Way
Manchester, Georgia 31816